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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,750	02/02/2001	Berend Jongsma	AHP-98248 PI	9381

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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No. 09/775,750	Applicant(s) JONGSMA ET AL.	
	Examiner Shanon A. Foley	Art Unit 1648	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☒ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *see attachment for discussion*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1-22*.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: *Supplemental IDS in paper no. 7*

DETAILED ACTION

Response to request for reconsideration

In response to the final rejection, applicant argues that the previous amendment to the claims do not constitute new matter because the amended claims explicitly recite what is implicitly taught in the specification. Applicant further cites Hansgirg v. Kemmer, 102 F .2d 212, 214, 40 USPQ 665 (CCPA 1939) to support their argument.

Applicant's arguments and a review of the cited case law have been considered. However, arguments are found to be unpersuasive because the original disclosure does not mention or remotely suggest that the instant vaccine formulations are not serially passaged. This situation is similar to that seen in Purdue Pharma L.P. v. Faulding Inc., 230 F .3d 1320, 56 USPQ2d 1481, 1487:

> What the '360 patentees have done is to pick a characteristic possessed by two of their formulations, a characteristic that is not discussed even in passing in the disclosure, and then make it the basis of the claims that cover not just those two formulations, but any formulation that has that characteristic. This is exactly the type of overreaching the written description requirements were designed to guard against. See Vas-Cath, 935 F.2d at 1561, 19 USPQ2d at 1115 ("Adequate description of the invention guards against the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.") (quoting Rengo Co. v. Molins Mach. Co., 657 F.2d 535, 551, 211 USPQ 303, 321 (3rd Cir. 1981)).

Therefore, since the specification does not imply or suggest that the instant vaccines are not or cannot be derived from serial passage and because there is ample support in the specification for using any commercially available IBV vaccine (which may be derived by some means of attenuation by passaging), the new matter objection is maintained for reasons of record.

Applicant's arguments with respect to claim objections for claims 21 and 22 are persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-13, 15, 16, 18, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Wakenell et al. for reasons of record.

As discussed above, applicant's arguments are considered unpersuasive because a non-serially passaged vaccine introduced by the amendment of paper no. 5 is new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-6, 14, 17, 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakenell et al. for reasons of record.

Applicant argues that Wakenell et al. teaches that serially dilution of the vaccine did not "significantly improve either hatchability or survival", and therefore, does not suggest the reduced concentrations instantly claimed. (For the record, this passage is found in the first column on page 935.)

Applicant's arguments are unpersuasive because the claims do not recite administering a serially diluted vaccine. Furthermore, in the vaccine art, it is a matter of routine to optimize dosages for protection. Therefore, the rejection is maintained because it is prima facie obvious for the ordinary artisan to use routine optimization for vaccine purposes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF
December 3, 2001

James C. Housel 12/17/01
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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